CHIENMAX VIETNAM CO.,LTD

K103675

KM 8, PHAM VAN DONG ROAD, HAI THANHDOUNG KINH DISTRICT
HAI PHONG, HAI PHONG, TAHNH PHO, 18671, VIETNAM

TEL:84-313632888 FAX: 84-31336288

OCT - 3 2011

EXHIBIT #3

510(k) Summary

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

Date: August 25, 2011

1. **Applicant:**
   Chienmax Vietnam Co. Ltd
   Km 8, Pham Van Dong Road,
   Hai Thanhdoung Kinh Districthai Phong,
   Hai Phong, Tahnh Pho, 18671, Vietnam

2. **Manufacturer:**
   Chienmax Vietnam Co. Ltd
   Km 8, Pham Van Dong Road,
   Hai Thanhdoung Kinh Districthai Phong,
   Hai Phong, Tahnh Pho, 18671, Vietnam

3. **Submitter:**
   Mr. Jigar Shah
   Official Correspondent for
   Chienmax Vietnam Co. Ltd

4. **Address:**
   mdi Consultants, Inc.
   55 Northern Blvd., Suite 200
   Great Neck, New York 11021
   Tel: 516-482-9001
   Fax: 516-482-0186
   Jigar@mdiconsultants.com

5. **Trade/proprietary Name:**
   Chienmax Vietnam Co. Ltd Powder-free Blue Nitrile Patient Examination Gloves.

6. **Common Names:**
   POWDER-FREE Patient Examination Glove

7. **Classification name:**
   Device Class I, Patient examination glove (21 CFR 880.6250, product code LZA)

8. **Predicate Devices:**
   - Sunmax Vietnam Co. Ltd Powder free Nitrile Patient Examination Gloves. **(K101870)**

- ULTRAWIN SDN BHD Non-Sterile Powder Free Nitrile Examination Gloves **(K 090828)**
- PT. MAHAKARYA INTI BUANA Powder Free Black Nitrile Examination gloves. **(K090464)**

9. **Device Description:**
Chienmax Vietnam Co. Ltd Powder Free Blue Nitrile Patient Examination Gloves are Class I disposable device which are made up of nitrile synthetic rubber , intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner and which meets all of the requirements of ASTM standard D6319 00a (2005).

10. **Intended Use:**
A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.

11. **Substantial Equivalence Discussion:**

A powder free patient examination glove is substantially equivalent to the predicate devices.

Characteristic and parameters	**Chienmax Vietnam Co., LTD** Powder Free Blue Nitrile Examination Glove **(New Device)**	**Sunmax Vietnam Co. Ltd** Powder free Nitrile Patient Examination Gloves. **(K101870)**	**ULTRAWIN SDN BHD** Non-Sterile Powder Free Nitrile Examination Gloves **(K 090828)**	**PT. MAHAKARYA INTI BUANA** Powder Free Black Nitrile Examination gloves. **(K090464)**	**SE Comparison**
Product Code	LZA	LZA	LZA	LZA	
Intended Use	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	SE
Width (size medium)	95	89	93-98	97.7	Minor Difference

verall length	244	240	240	240.9	Minor Difference
Palm thickness	0.113	0.12	Min 0.08	0.109	Minor Difference
Finger thickness	0.138	0.12	Min 0.08	0.148	Minor Difference
Tensile strength pre aging min	16.78	22	15 - 21	18.8	Minor Difference
Tensile strength after aging min	17.40	23.6	14-22	21.3	Minor Difference
Ultimate elongation pre aging min	510	500	550 - 630	679.4	Minor Difference
Ultimate elongation after aging	555	500	520 - 610	767.4	Minor Difference
Meets Biocompatibility	yes	Yes	Yes	Yes	SE
Duration of bio-compatibility	Limited	Limited	Limited	Limited	SE
Skin irritation test	Passes	Passes	Passes	Passes	SE
Dermal ensitization	Passes	Passes	Passes	Passes	SE
Residual powder test	Passes	Passes	Passes	Passes	SE
Labeling	Identical	Identical	NA	NA	Minor Difference

12. Summary of Testing:

	Test	**Results**
a.	Dermal Sensitization Test	Passes
b.	Primary Skin irritation	Passes
c.	Permeation testing per ASTM D 6978-05	Passes
d.	Iodine Test	Passes
e.	Tensile strength	Gloves meets the requirements of ASTM D63 19-00a.
f.	Barrier strength	Gloves meets the requirements of ASTM D63 19-00a.

The standards used by Chienmax Vietnam Co. Ltd to determine substantial equivalence are based on ASTM D 631900a-2005. All testing meets requirements for physical specifications and dimensions conducted on gloves, Inspection level S-2, AQL 4.0, pinholes at AQL 2.5

There are no special labeling claims and we do not claim our gloves to be hypoallergenic.

13. Conclusion:

Based on the nonclinical tests performed the Chienmax Vietnam Co. Ltd Powder-free Blue Nitrile Examination Glove is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G609
Silver Spring, MD 20993-0002

Chienmax Vietnam Company, Limited
C/O Mr. Jigar Shah
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

OCT - 3 2011

Re: K103675
Trade/Device Name: Chienmax Vietnam Company, Limited Powder Free Blue Nitrile Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: September 20, 2011
Received: September 22, 2011

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT #1

Indications for Use

510(k) Number (if known): K103675

Applicant: Chienmax Vietnam Co. Ltd

Device Name: Chienmax Vietnam Co. Ltd Powder Free Blue Nitrile Patient Examination Gloves.

Indications for Use:

A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.

Prescription Use_____ **AND/OR** **Over-The-Counter Use __X__**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103675